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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,253	ROWE ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *33-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-23,25-32 and 52* is/are rejected.

7)☐ Claim(s) *4,5,9,12,13,24,26-28 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-52 are pending.

Election/Restrictions

1. Claims 33-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II-IV, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. filed November 5, 2003.

2. Applicant's election with traverse of Group I, claims 1-32 and 52 in Paper No. dated November 5, 2003 is acknowledged. The traversal is on the ground(s) that the examination of the entire application cannot constitute a serious burden. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1)independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-IV are drawn to distinct inventions which are related as separate products capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Group I is directed to microorganisms, Group II nucleic acids, Group III antibodies and Group IV a method of screening potential agents, each group evidencing a independent and distinct biological structure, function and biological effect. In the instant case a burden has been established in showing that the inventions of Groups I-IV could be and are classified separately necessitating different searches of issued US Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example antibodies, of Group III, are structurally and functionally distinct from the microorganisms of

Group I. Additionally, it is submitted that the inventions of Groups I-IV have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/AU00/00805, filed July 3, 2000, which claims priority back to July 2, 1999.

Sequence Compliance

4. The instant Application is now in sequence compliance.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 16, 18,19, 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. US Pat. 6,303,572. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species of method, the method being associated with specific microorganisms (see '572, claims 2-4, and 8) and specific species of lactic acidosis

conditions (see '572, claims 5-7,9-15) and immunize through administering for the treatment of treating species of lactic acidosis associated diseases (see Rowe, US Pat. '572, see claims 5-15); the allowed species anticipates the instantly claimed genus of methods that immunizes through administering any composition that serves to induce an immune response for treating any lactic acidosis condition.

7. Claims 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,290,767. Although the conflicting claims are not identical, they are not patentably distinct from each other because The allowed species of method that administers a specific active agent for the treatment of treating lactic acidosis (see Rowe, US Pat. '767, abstract and all claims) anticipates the instantly claimed genus of methods that administers any active agent for treating lactic acidosis.

8. Claims 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,468,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because The allowed species of method that administers a specific active agent for the treatment of treating lactic acidosis and controlling endotoxin accumulation in the gastrointestinal tract(see Rowe, US Pat. '964, abstract and all claims) anticipates the instantly claimed genus of methods that administers any active agent for treating lactic acidosis, the agent being one that is not the allowed species of invention which also must have the functional characteristic of controlling endotoxin accumulation; the allowed species anticipates the instantly claimed genus of methods.

Claim Objections

9. Claim 24 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend from other claims in the alternative, and not two claims simultaneously. See MPEP § 608.01(n). Accordingly, the claim 24 will not been further treated on the merits.

10. Claims 4, 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

11. Claim 4 recites the phrase "wherein the vertebrate is selected from the group consisting of"; the recitation of various vertebrates is not further limiting of the claimed vaccine compositions of microorganisms or fragments thereof. No vertebrate proteins are contained in the vaccine. Claim 4 is not further limiting of claim 1.

12. Claim 5 recites the phrase "dead intact cells" and depends from claim 1 which recites the phrase "said microorganism is capable of producing lactic acid". Dead cells are not capable of producing lactic acid, thus broadening the scope of claim 1 directed to compositions of microorganisms with the recited capability.

13. Claim 9 is objected to because of the following informalities: Claim 9 recites Markush language "selected from the group consisting of" and sets forth various species of invention in the general form A, B and C, but also includes the phrase "together with a pharmaceutically acceptable carrier, adjuvant and/or diluent". The phrase"together with a pharmaceutically

acceptable carrier, adjuvant and/or diluent" should precede the recitation of the Markush language introductory phrase "selected from the group consisting of". This objection could be obviated by amending the Markush group to no longer include the species a pharmaceutically acceptable carrier, adjuvant and/or diluent. Appropriate correction is required.

14. Claim 12 recites the phrase "attenuated cells, killed whole cells, cell lysate, crude antigen mixture or purified antigen or antigens from the microorganism" and depends from claim 9 which recites the phrase "at least one isolated microorganism capable of producing lactic acid". The attenuated cells, killed whole cells, cell lysate, crude antigen mixture or purified antigen or antigens from the microorganisms" are not capable of producing lactic acid, thus broadening the scope of claim 9 which directed to compositions of microorganisms with the recited capability.

15. Claim 13 depends from claim 9 and recites the phrase "microorganism and/or fragment or fragments thereof", while claim 9 recites the phrase ""at least one microorganism capable of producing lactic acid within the gut of a vertebrate, or fragment, or fragments thereof". The combination of a microorganism and a fragment or fragments is not set forth in claim 9 from which claim 13 depends, as claim 9 defines the composition to comprise one or more microorganisms, or one or more fragments, but not the combination of both. Claim 13 broadens the scope of claim 9, and is therefore not further limiting of the base claim.

16. Claims 26-28 and 30 are objected to because of the following informalities: Claims 26-28 recite the singular tense while claim 25 recites plural tense of what is being claims; is the tense intended to be the plural or singular form in the administered compositions? Claim 30 recites the term "5HT" and "NO"; the meaning of these terms is not clear; utilization of

abbreviations in the claims is permitted upon the definition of the abbreviation in the claims at its first appearance. Appropriate correction is required.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 2-3,10, 11, 22,23 and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for various compositions that comprise the recited bacteria, does not reasonably provide enablement for the specific isolate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use novel strains with unobvious characteristics the invention commensurate in scope with these claims.

The claims are directed to specific strains and species of microorganism, that need a perfected deposit in order to enable the claimed invention. For each deposit made pursuant to the Budapest Treaty regulations, shall contain:

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

(e) Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section

must be filed before or with the payment of the issue fee (see § 1.312).

[Added, 54 FR 34882, Aug. 22, 1989, effective Jan. 1, 1990; paras. (b) and (c) revised and para. (e) added, 66 FR 21092, Apr. 27, 2001, effective May 29, 2001]

This rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

19. Claim 1-23, 25-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for whole living compositions of microorganisms that reduce lactic acidosis, specific agents that reduce lactic acidosis conditions, and specific immunogens that will induce an immune response that will specifically inhibit the production of lactic acidosis does not reasonably provide enablement for any fragment or fragments of any of the recited microorganisms to function as a vaccine or pharmaceutical component of a pharmaceutical composition administered to an animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification fails to teach how to formulate and use the claimed vaccines that comprise any fragment or fragments of a microorganism. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity against the lactic acidosis causing microorganism, thus preventing infection and/or disease induction.

The specification does not provide substantive evidence that any fragment or fragments of any of the recited microorganism can function as vaccines or pharmaceutical compositions that are capable of inducing protective immunity in the claimed methods. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose

of preventing lactic acidosis. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines that comprise any fragment or fragments of the recited microorganism, i.e. would not be able to accurately predict if protective immunity has been induced.

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the at protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

The specification fails to teach the identity the claimed fragment or fragments compositions with the claimed characteristics, i e. capable of treating lactic acidosis. Further, the specification fails to provide an adequate written description of the genus of fragment or fragment containing vaccine/pharmaceutical composition that serve the recited intended used, the skilled artisan would be required to de novo locate, identify and characterize the claimed other proteins. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to other surface proteins with the claimed characteristics.

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 1-23,25-32 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

22. Claims 1-23,25-32 and 52 recite the phrase "wherein in said microorganism is capable of producing lactic acid within the gut of said vertebrate". In view of the fact that the claimed vaccine is for prevention of lactic acidosis and the claimed microorganism produce lactic acid, it appears that the microorganisms in the vaccine would cause the problem rather than prevent it. Clarification of the recited intended use "prevention of lactic acidosis" of the vaccine is requested.

23. Additionally, claims 1-23,25-32 and 52 recite the phrase "fragment or fragments" that are in a vaccine, the vaccine being able to prevent lactic acidosis; what are the claimed fragments? As the structure or biological function of the fragments which evidence the recited capability is not set forth in the claims. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

24. Claims 1-23, 25-32 and 52 recite the term "like". The American Heritage Dictionary of English , Fourth Edition, 2000, defines the term like to mean "possessing the characteristics of; resembling closely; similar to." The term "like" in claims 1-23, 25-32 and 52 is a relative term which renders the claim indefinite. The term "like" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the

art would not be reasonably apprised of the scope of the invention. What characteristic or characteristics is required to function as a vaccine in the claimed microorganism, fragment or fragments of the microorganisms that are like the recited bacteria is unclear.

25. Claims 3, 11, 23 and 52 recites various abbreviations, the abbreviations being set apart from the claim limitations in brackets. What the scope of the recited terms in brackets is unclear and what the meaning of the recited abbreviated terms set forth is also unclear. What is the scope of the claims? The meets and bounds of the claims which recite the abbreviations and brackets can not be ascertained as it is not clear whether what is set off by the brackets is apart of the claim or not.Claim 6 recites the phrase "outer membrane and associated proteins"; this phrase lacks antecedent basis in claim 1 from which it depends. Amendment of claim 6 to recite—wherein said fragment or fragments comprises outer membrane and associated proteins of said microorganisms—or an equivalent phrase similar to the claim limitations set forth in claim 7.

27. Regarding claims 7 and 14, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

28. Claim 13 recites "wherein the microorganism" "is present as outer membrane and associated proteins ". A microorganism is made of many different parts and proteins, but the individual parts or proteins is NOT the microorganism. According to Stedmann's Medical dictionary, the term "microorganism" is : A microscopic organism (plant or animal). A outer membrane and associated proteins is not a microorganism. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so

as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "outer membrane and associated proteins" in claims 12-13 is used by the claim to mean "microorganism", while the accepted meaning is "microscopic plant or animal." The term is indefinite because the specification does not clearly redefine the term.

29. Claims 20-23 recites the phrase "an active agent". The activity of the active agent is not defined, by any specific structure or known biological function. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

30. Claims 27-29 recite the term "bacteria" ; this term lacks antecedent basis in claim 25 which recites the term microorganism.

31. Claim 25 recites the term "active agent" and depends from claim 19 which recites the limitation "microorganism" ; there is insufficient antecedent basis for this limitation in claim 19; claim 25 broadens the scope of claim 19 by redefining what is administered.

32. Claim 26 defines the antibiotics to be active against gram positive microorganisms, and indirectly depends from claims 1 and 10 which also recite gram negative microorganisms. . It is unclear how the active agent of claim 26 corresponds to the recited gram negative bacteria in the compositions set forth in claims 1 and 10. How claim 26 is further limiting of the genus of gram negative compositions defined in claims 1 and 10 is unclear.

33. Claim 27 defines the active agent to interact with gram negative bacteria and indirectly depends from claims 1 and 10 which also recite gram positive microorganisms. It is unclear how the active agent of claim 27 corresponds to the recited gram positive bacteria in the compositions set forth in claims 1 and 10. How claim 27 is further limiting of the genus of gram positive compositions defined in claims 1 and 10 is unclear.

34. Claim 29 recites the phrase"indirectly active against lactic acid producing gram negative bacteria" and indirectly depends from claim 19 which recites compositions of gram positive bacteria through depends upon claims 1 and 10 which recite Streptococcus. It is unclear how the active agent of claim 29 corresponds to the recited gram positive bacteria in the compositions set forth in claims 1 and 10. How claim 29 is further limiting of the genus of gram positive compositions defined in claims 1 and 10 is unclear.

35. Claim 32 recites the phrase "yeast and mycelial preparations"; these terms lack antecedent basis in claim 31 from which claim 32 depends. This rejection could be obviated by amending the claim to recite –further comprises--.

Claim Rejections - 35 USC § 102

36. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

37. Claims 1-4, 6-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Leer et al (WO97/14802).

Leer et al disclose the instantly claimed invention directed to compositions that comprise a fragment of a lactic acid producing microorganism, specifically a 29 kDa bacterial protein from Lactobacillus fermentum 104R (see page 17, lines 15-16), and peptide fragments thereof (see page 23, paragraph v) and page 25, lines 13-24). The protein or polypeptide induces an immune response as it immunoreacts with polyclonal and monoclonal antibodies (see page 30, claim 13).

The protein, polypeptide or fragment was disclosed and claimed to be in combination with a pharmaceutically acceptable dosage form (see claim 29, page 33), which includes forms for topical, oral, intravenous administration (see page 10, lines 31-39 and page 11, lines 1-3).

The disclosed pharmaceutical compositions (see page 11, lines 28-31) are for administration to a vertebrate (human, pig, mouse, see all examples) .

The disclosure teaches a method of improving food products the importance of administering the composition to interfere with adhesion of gastrointestinal, urogenital, oral, nasal and respiratory pathogens (see page 8, lines 7-15).

The disclosed adhesion protein serves to combat bacterial infections associated with Clostridium (see page 10, lines 5- 22 (Clostridium, being a gram positive microorganism)) and is therefore a Clostridium-like strain of Lactobacillus which produces a protein or polypeptide which serve to prevent undesired effects caused by Clostrium-like strains of microorganism through preventing colonization by blocking adhesin to host cell receptors.

The reference anticipates the instantly claimed compositions that comprise a fragment or fragments of a Clostridium like species. The recited intended use of the claimed invention does not distinguish over the applied prior art, because the microorganism fragment was obtained and formulated into a composition from a lactic acid producing microorganism, and is able a prevent the first step of infection through blocking mucosal colonization of pathogenic microorganisms (see entire abstract).

38. Claims 1-23, 25-32 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by (WO99/00136 ; publication date January 7, 1999).

(Instant claims 1-7, 9-15) WO99/00136 disclose compositions which comprise whole living cells of Bacteroides-like species, Selenomonas species (see page 43, claim 14), Enterococcus (see page 43, claim 18), Streptococcus species (see page 43, claim 18; specifically Streptococcus bovis: see page 43, claims 19-20), as well as additional probiotic strains of bacteria (see page 43, claim 14), singularly or in combination (see page 7, line 11), to include adjuvants, specifically cytokine adjuvants (see page 11,line 9) and an active agent (see glycopeptide, page 4, lines 21-28). (Instant claim 8) The compositions are formulated as vaccines (veterinary or pharmaceutical compositions (see page 7, line 17) for administration by intra-muscular or sub-

cutaneous injection (see page 11, paragraph 3). (Instant claim 52: in light of the rejection under 35 USC 112, second paragraph with respect to the presence of brackets in the claim, and the deposit requirements under the Budapest treaty not being perfected) WO 99' anticipates isolated cultures of the recited microorganisms in claim 52 (see page 7, lines 3-4, page 6, line 35; see page 10, lines 36-38; page 11, lines 1-13).

(Instant claims 16-20, 25-30) WO99/00136 disclose the instantly claimed invention to a method for the treatment and/or prophylaxis of lactic acidosis in a vertebrate, the method comprising the step of

immunizing (see page at least page 11, lines 25-30) or administering to said vertebrate a therapeutically effective amount of a vaccine (see pages 4-ll; especially page 6, lines 35-37; page 7, lines 10-11) in combination with additional active agents); the active agent is an "antibiotic, enzyme preparations, clay preparations, compounds which slow the digesta flow rate and probiotic preparations (see page 41, claims 2-14)", and an adjuvant (the adjuvant being a cytokine, see page 11, lines 9-10). Active agents are disclosed at pages 4, lines 16-38 through page 6, lines 1-16). (Instant claims 31-32) The compositions also includes probiotic bacterial preparations of Megasphera, Veillenolla, Selenomonas, Propionibacterium, Anaerovibrio and Peptococcus (see page 7, lines 2-4) which may be used individually, or in combination together (see page 7, line 4-11).

(Instant claims 21-23) The reference also discloses the claimed method for the treatment and/or prophylaxis of lactic acidosis in a vertebrate, the method comprising the step of :

administering to said vertebrate a therapeutically effective amount of an active agent (see abstract) capable of preventing or controlling lactic acid accumulation in the gut of the vertebrate (see all claims, pages 41-44), wherein the active agent is an "antibiotic, enzyme preparations, clay preparations, compounds which slow the digesta flow rate and probiotic preparations (see page 41, claims 2-14).

39. Claims 1-4, 7, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al (US Pat. 4,906,612) as evidenced by US Pat. 6,429,006

Hayashi et al disclose a composition that comprises a fragment of a microorganism, the microorganism fragment being a glycopeptide (see col. 1, lines 5-6) isolated from Bacillus subtillis (see col. 4, lines 25-27), a lactic acid producing bacteria (as evidenced by US Pat. 6,429,006 : "the genera Lactobacillus, Bacillus and Rhizopus produce L (+) –lactic acid."); Bacillus subtilis being like the recited bacterium through production of lactic acid. The glycopeptide serves to promote growth of animals (see title, col. 2, lines 27-42), including sheep, goats, cows, pigs, chickens, turkeys, ducks, rabbits and domestic animals (see col. 3, lines 22-27) through improved feed utilization efficiency (see col. 3, lines 39-41). The reference anticipates the instantly claimed invention.

40. Claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Leedle et al (US Pat 5,380,525) . Please Note: the examiner is reading the phrase "active agent" to encompass any agent with the recited functional characteristics.

Leedle et al disclose a method for the treatment and/or prophylaxis of lactic acidosis in a vertebrate, the method comprising the step of :

administering to said vertebrate a therapeutically effective amount of an active agent (a biologically pure bacterial culture of Megasphaera elsdenii, see col. 2, lines 15-22; lines 26-31) capable of preventing or controlling lactic acid accumulation in the gut of the vertebrate (see Leedle et al, title, claim 4). The reference anticipates the instantly claimed method.

Conclusion

41. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and are considered to be duplicative of the art applied against the claims above:

42. Argoudelis et al (US Pat. 5,981,234; US Pat. 5,695,984); Baylis et al (US Pat. 4,393,046); Ishihara et al (US Pat. 4,276,286); Garner et al (US Pat. 5,529,793) Gillin et al (US Pat. 4,237,116); Huber (US Pat. 4,112,069) Muir et al (US Pat. 4,061,732, control of lactic acidosis in ruminants); Reid et al (US Pat 6,613,549); Spangler et al (US Pat. 6,524,574);Spries (US Pat. 4,394,377); Ware et al (US Pat. 5,534,271).

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703) 308-7543. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703)308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Vgp
January 22, 2004

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